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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/955,657

Applicant(s)

WOOLEY ET AL.

Examiner

Micah-Paul Young

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 09 September 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 23-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-53 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                               | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3 and 5</u> . | 6) <input type="checkbox"/> Other: _____                                    |

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### DETAILED ACTION

**Acknowledgment of Papers Received:** Election received 09/09/02

#### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1 – 22, drawn to a method of inhibiting microbial growth in a skin injury, classified in class 424, subclass 405.
  - II. Claims 23 – 49, drawn to a medical dressing comprising an antibacterial composition, and method for its use, classified in class 424, subclass 443.
  - III. Claims 50 - 53, drawn to a kit for preparing an antimicrobial composition, classified in class 424, subclass 400.
2. Applicant's election with traverse of group I in Paper No. 7 is acknowledged. The traversal is on the ground(s) that there would be no excessive burden of search on the examiner. This is not found persuasive because the method of group I does not require the medical dressing of group II nor the instructional kit of group III. Group I recites only a method of inhibiting microbial population comprising contacting a composition to a wound site. No mention of a medical dressing is made in the generic claim 1. Also the medical dressing of group II recites the intended use of “delivering an antimicrobial composition to a skin injury or lesion”. Applicant is reminded that an intended use does not impart patentability to a composition. The medical dressing could be used simply as a support to non-injured skin. Neither groups require an instructional kit described in group III, in view of knowledge in the art as to how to prevent infection in a skin injury. The method of group I provides ample instructions to a skilled artisan as to how to inhibit microbial proliferation in a skin injury. As earlier stated the limitation of

group II that the medical dressing is used for the delivery of antimicrobial compositions to skin injuries is an intended use, requiring no further instructions. It is the position of the examiner that the three groups represent distinct groups.

The requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3 – 5, 7, 8, 10, 12, 14, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Palladino et al (USPN 5,055,447). The claims are drawn to a method of treating a microbial infection in a skin wound. The method comprises applying a compound comprising an antimicrobial agent, a chelating agent, a pH buffer and a carrier. The claims recite specific chelating agents and antimicrobial agents all well known in the art. The claims also recite the skin wound to be a burn.

Palladino et al teaches a method of treating and preventing infections and septic shock in burn patients. The method comprising administering a compound comprising antimicrobial agents, chelating agents, carriers and a pH buffer. The antimicrobial agents are selected from a list consisting of amikacin, tobramycin and gentamicin; the chelating agent is disclosed as EDTA, while sodium acetate acts as the buffer. Also the composition works against gram-negative bacteria such as *E. Coli* and *Pseudomonas aeruginosa* (Abstract; col. 5, lin. 40 – 57;

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col. 7, lin. 23 – 43, 61 – 68; Examples). These disclosures along with other render the claimed invention anticipated.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1 – 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palladino et al (USPN 5,055,447) in view of Martin (USPN 5,863,938), Friedman et al (USPN 5,160,737), Azzariti (USPN 4,438,099), Nelson (USPN 4,323,558), and Huber et al (USPN 3,758,682).

8. As stated the claims are drawn to a method of treating a microbial infection in a skin wound in a patient. The method comprises applying a compound comprising an antimicrobial agent, a chelating agent, a pH buffer and a carrier. The claims recite specific chelating agents and antimicrobial agents all well known in the art. The claims also recite the skin wound to be a burn, ulcer or an abrasion. The composition further comprises vitamin E.

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9. As discussed above Palladino discloses a method of treating infection comprising administering a composition comprising a chelating agent, an antimicrobial agent, a ph buffer and a carrier. Palladino however does not disclose all of the antimicrobial agents as recited by applicant, nor does it disclose the same ph buffer as recited by applicant. Palladino also does not specify whether the agents were affective against specific Gram-positive bacteria. Another deficiency in the reference is its silence to the inclusion of vitamin E, or a possible form the composition can take such as a mouthwash.

10. With regard to the vitamin E limitation, it is common to include vitamins into topical wound healing preparations, to provide essential nutrients to the skin during the healing process or to act as a carrier for the healing composition. This is shown by Martin which teaches an antibacterial wound healing preparation which inhibits infection during the healing process by including antibiotics such as oxytetracycline, neomycin, and includes vitamin E (col. 11, lin. 29 – 55; col. 48, lin. 20 – 40). A skilled artisan is motivated to include such anti-oxidant agents into wound healing preparations in order to provide such properties to the composition and to provide nutrients to the wound site.

11. The remaining deficiencies are merely a matter of selecting equivalent or well-known species of components. Friedman teaches a method for treating an infection with a liquid polymer wound healing composition comprising neomycin, and other antibiotics. The composition has an embodiment, which treats oral mucosal wounds and is in the form of a mouthwash (col. 13, lin. 65 – col. 14, lin. 7; Examples).

12. The selection of specific antibiotics because of their particular effectiveness against specific bacteria is well known in the art and is merely the selection of an equivalent species. As

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seen in Azzariti, which teaches a method for treating infections in burns and ulcers, by using antibiotic agents which are active towards Gram-Positive bacteria such as *Staphylococcus* (Examples), this practice of determining which bacteria are affected by which agents is well within the level of one of ordinary skill in the art, and does not impart patentability.

13. The selection of equivalent species continues in applicant's recitation of the chelating agents and the pH buffer. TRIEN is a well-known chelating agent in the art as seen in Nelson. Nelson teaches a composition for wound healing comprising TRIEN and various antibiotic agents such as penicillins, erythromycins and tetracyclines (col. 3, lin. 11 – 24; Examples). The selection of a pH buffer is well within the skill of the art, as seen in Huber et al which teaches a composition which has wound healing properties, which also included such antibiotics such as neomycin and or tetracyclines (col. 13, lin. 23 – 34).

14. With this in mind a skilled artisan would have been motivated to follow the suggestions and teachings in the art in order to improve a method of treating or preventing infections in wounds. A skilled artisan would have combined the teachings of Palladino with those of Martin in order to include an antioxidant in the composition to provide a beneficial effect to the skin. A skilled artisan would have followed the suggestions of Friedman to combine these components together in order to treat oral injuries and inhibit bacterial infection in the form of a mouthwash. This artisan would have than simply selected equivalent species of well-known components such as the antibiotics and pH buffer of Huber, the chelating agent of Nelson, and the bacteria effecting knowledge shown in Azzariti. It would have been obvious to a skilled artisan at the time of the invention to combine the knowledge and suggestions of these references with an expected result of a method for treating and preventing bacterial infection in wounds.

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*Conclusion*

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Schmitt (USPN 4,122,158) teaches a method of treating surface wounds including applying a composition comprising antibiotics. Polk, Jr. et al (USPN 5,198,212) teaches a method of treating wounds where the composition comprises antibiotics, among other components.

*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young  
Examiner  
Art Unit 1615

M. Young  
December 9, 2002

  
CARLOS AZPURU  
PRIMARY EXAMINER  
GROUP 1500